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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/424,519 | 03/03/00 | MITCHELL | J 175931 |

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CHICAGO IL 60601-6780

HM22/0524

| EXAMINER |
|----------|
| KWON, B |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1614 | 10 |

DATE MAILED: 05/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/424,519

Applicant(s)

MITCHELL ET AL.

Examiner

Brian-Yong S Kwon

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Office Action Summary

- I. The rejection of claims 1-3, 22, 24 and 26 under 35 U.S.C. 112, 1st paragraph will not be maintained in light of Response filed on May 7, 2001.
- II. The rejection of claims 1-3 under 35 U.S.C. 102(b) will be maintained. Applicant could overcome this rejection by deleting "prophylactic or", "prevent or", and "prevention or" in claim 1.
- III. The rejection of claims 24-27 under U.S.C. 103(a) will be maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Monti et al. (PAACR Annual Meeting, vol.36, no. 0, 1995).

This rejection is analogous to the original rejection of claims 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monti et al. (PAACR Annual Meeting, vol. 38, no. 0, 1997) in view of Harris et al. (J. Natl Cancer Inst 1996;88;1442-55).

This rejection is analogous to the original rejection of claims 24-27.

Response to Arguments

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Applicant's arguments filed on May 7, 2001 have been fully considered but they are not persuasive.

Applicant's argument takes position that "Novitski is directed to a situation in which the primary reference that was being cited by an Examiner as a basis for an obviousness rejection disclosed every element of the claimed method. The primary reference, however, did not expressly disclose an inherent property of the active agent. Secondary references were cited to provide the teaching of the inherent property...". Applicant's arguments are not well taken. Contrary to applicant's argument concerning "the reference cited as a basis for rejection, namely Monti I, does not teach and, therefore, does not enable, a method of treating an animal, let alone a method of using a nitroxide, or a prodrug thereof...", claim 1 reads on prophylactic use of claimed product. Applicant's recitation of terms "propylactic or" "prevent or" and "prevention or" in claim 1 are directed to preventing a malady or disease with old and well known compounds or composition such as Tempol. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth haec verba are not probative prior use clearly anticipates such utility, absent limitations distancing such claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification utilities will not be successful. At page 1391, Ex parte Novitski, supra, the board said "we are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow". In the instant application, applicant's failure to distance the claims from the cited reference makes the claims anticipated by such reference. Thus for the above reasons the rejection of claims 1-3 under 35 U.S.C. 102(b) maintained.

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Applicant's argument takes position that "the ordinarily skilled artisan would not have arrived at a method of treating cancer in an animal prophylactically or therapeutically in accordance with the present invention. In addition, one of ordinary skill in the art would not have had a reasonable expectation, based on an in vitro showing of Tempol inducing apoptosis in leukemic cell lines, of success in vivo". The examiner disagrees. It is old and well known in the art to employ an agent that is effective in vitro study into vivo study to monitor its efficacy. Monti II clearly shows the positive teaching of the cytotoxic effect of Tempol in human leukemic cells via induction of apoptosis. The reference also suggests that "similar effects might be elicited in tumor cell lines".

Furthermore, one having ordinary skilled in the art would have motivated to treat cancer that is frequently harbor p53 mutations (See page 10, lines 41 of Harris et al.) by the inhibition of tumor growth by apoptosis.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Monday through Friday from 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mariann Cintins, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

